

STUDENT ASSENT FORM

TITLE: Zinc Fortification Effects on Cognition, Psychoeducational Performance, Body Composition, Physical Fitness and Immune Function of Adolescents

INSTITUTION: USDA, ARS, Grand Forks Human Nutrition Research Center
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Who is doing this research study?

This research study is being done by the Grand Forks Human Nutrition Research Center (**GFHNRC**), which is part of the United States Department of Agriculture. The main people doing this study are two scientists who work at the GFHNRC. Dr. James Penland is a research psychologist who studies how nutrition affects behavior. Dr. Hank Lukaski is a research physiologist who studies how nutrition affects body composition (fat, muscle and bone) and physical fitness. Other people who also work at the GFHNRC will help the two scientists conduct the study.

Why are we doing this study?

Zinc is a common mineral found in our diets, the foods we eat and the fluids we drink. About 40 years ago, researchers discovered that zinc was needed for normal growth in children about your age. Since that time, all of the studies have been done with younger children or adults. For example, in studies with first and second grade children, adding 20 milligrams of zinc to the diet each day improved their ability to solve problems and their eye-hand coordination. In studies with adults, adding 30 or 50 milligrams of zinc to the diet each day improved their memory. Other studies have found that zinc may affect body composition, physical fitness and immunity (the body's ability to fight disease), but none of these studies were done with children your age.

This study will help find out whether eating more zinc can help children your age to do better in school, to be more physically fit, and to have better health.

Can I take part in this study?

You can participate in this study if you are in the 7th grade and attend a Grand Forks Public School during the 2002-2003 school year. Both you and your parent or guardian must agree and want to take part in the study. Also, if you take any dietary supplements (like Flintstones), you must agree to stop taking those supplements while you are in the study. If you have an allergy to or cannot drink the orange or apple juice being served in this study (described below), then you cannot participate.

How will my parent/guardian take part in the study?

Your parent or guardian will be asked to fill out several forms and questionnaires to give us some basic background information like when you were born and how many brothers and sisters you have, and information about your current and past health. Your parent or guardian will also keep a record of any illnesses and injuries you might have during the study, and will complete a questionnaire like one that you will be asked to complete.

What will I have to do, when, and how long will it take?

You will be given one of three dietary treatments (described below) for about 12 weeks. Several measurements (described below) will be made during a 3-week period before the treatment and again during the last three 3 weeks of treatment. The study will be conducted between August and December 2002, and last about 15 weeks. All measurements will be made at your school, either in your classroom or on the GFHNRC's Mobile Nutrition Research Laboratory. All measurements will be made by an experienced, specially trained technician

from the GFHNRC. Some measurements will be done before school and some will be done during school hours; therefore you may miss part of several classes during the 15-week study. Because they believe the experience will be educational, teachers will give you permission to miss class time to take part in this study.

Dietary Treatment

The dietary treatment will be common orange or apple juice that contains: (A) no extra zinc, (B) 10 milligrams of extra zinc, or (C) 20 milligrams of extra zinc. You will be randomly selected to always get juice containing the same amount of zinc (A, B or C), but you will never know which of the three you are being given. Each of the three treatments will be given to at least 50 boys and 50 girls.

You will be given a 4-ounce cup of orange or apple juice to drink each regular school day for 12 weeks during the fall term of the 2002 school year. Juice will be handed out in your school lunchroom by GFHNRC staff. Your name will be used to identify you and make sure you get the correct juice each day. **YOU MUST DRINK ALL OF THE JUICE EACH DAY AS SOON AS IT IS GIVEN TO YOU.**

Dietary Intake

What you usually eat and drink will be measured in two ways. First, you will be asked to fill out a questionnaire asking how often (for example, daily, weekly or monthly) you eat certain foods or drink certain fluids (for example, water, soda pop or milk). You will complete the questionnaire once at the beginning and once at the end of the study, and it will take about 30 minutes each time. Second, you will meet with an interviewer from the GFHNRC who will ask you to recall (remember) what you ate and drank the previous day. You will meet with the interviewer two times during the study, and the meeting will take about 15 minutes each time.

Blood Draw

Blood will be drawn from your arm to measure zinc and other minerals and vitamins, and to measure your general health. Blood will be drawn with sterile needles and syringes similar to those used in your doctor's office or a clinic. Approximately 35 milliliters (2-1/3 tablespoons) of blood will be drawn twice, once at the beginning and once at the end of the study, for a total of 70 milliliters (4-2/3 tablespoons) during the 15-week study. This amount of blood is much less than what was drawn from children your age in a recent national study. **YOU MUST NOT EAT ANY FOOD OR DRINK ANYTHING OTHER THAN WATER AFTER 10 PM THE NIGHT BEFORE A BLOOD DRAW**, which will occur no later than 9:30 am the next morning. You will be given orange or apple juice and a snack after the blood draw, and watched for a short time to make sure you feel okay. Your parent or guardian will be notified if the results of your blood draw show any health problems.

Computer Tasks

You will be asked to do simple tasks on a personal computer to measure things like your attention, memory, problem solving, and eye-hand coordination. Examples of tasks include tapping a key on the keyboard as fast as possible, using a mouse to follow an object moving across the screen, searching a group of objects for two of a kind, learning and remembering lists of words or simple geometric patterns, and categorizing objects. This testing will occur once at the beginning and once at the end of the study, and take about 60 minutes each time.

Youth Self Report

You will be asked to fill out the Youth Self Report, a questionnaire like one your parent or guardian will complete. This questionnaire asks questions about your mental, physical and social abilities and skills, school performance, and any problems you may have. An experienced, specially trained GFHNRC technician will provide instructions for completing the questionnaire. You will complete the questionnaire once at the beginning and once at the end of the study, and it will take about 30 minutes each time.

Vision and Hearing Tests

To make sure that you do not have vision or hearing problems that might affect other measures we are making,

your vision and hearing will be tested using standard screening equipment and procedures. These tests take about 20 minutes total and will be done only once during the first 3 weeks of the study. You may take part in this study even if you wear glasses, contact lenses or a hearing aid.

Growth and Body Composition

Your growth and body composition will be measured in several ways. Your height and body weight will be measured by a stadiometer and scale just like those used in your doctor's office. The circumference (distance around) of your upper arm, waist, hip, thigh and calf will be determined with a tape measure and set of calipers. Skinfold thickness, a measure of body fat, will be determined by gently pinching the skin, holding the pinched area, then measuring the thickness of the pinched skin and fat tissue at the front and back of your upper arm, back, waist, thigh and calf with a set of calipers. You will wear your usual physical education uniform (shorts and short-sleeved shirt) but no shoes. Measurements at the waist, hip and thigh will be done through your clothing to reduce embarrassment. All growth and body composition measurements will be done behind a portable screen in the school gymnasium to protect your privacy. A female adult will always be present during measurements of girls. These measurements will be made once at the beginning and once at the end of the study, and take about 20 minutes each time.

Another type of measurement, known as bioelectrical impedance, will also be used to find out whether the treatment affects your body composition and whether this measure might be useful with children your age. You will lie on a table and electrodes will be taped on your shoulder, elbow, wrist, hip, knee, and ankle. A safe and painless low energy electrical current will be applied to the electrodes. This is the same amount of electrical current that you are exposed to when watching television or listening to the radio. You will not feel this current. The amount of bone, muscle, fat and fluids will be determined based on how your body conducts this electrical current. You will wear your usual physical education uniform (shorts and short-sleeved shirt) but no shoes or socks. These measurements will be made once at the beginning and once at the end of the study, and take about 10 minutes each time.

Physical Fitness

You will be asked to take part in a physical fitness test to measure your aerobic capacity, muscle strength and endurance, and flexibility. This test compares your activity patterns and fitness to national norms for school-aged children. These measurements will be made once at the beginning and once at the end of the study, and take about 2 hours (2 gym classes) each time.

How will my teachers and school be involved in this study?

Teachers will complete a questionnaire like the ones you and your parent or guardian will complete. Teachers and school administrators will develop new classroom activities that will help you learn more about nutrition, health, science and research as you take part in this study. The Grand Forks Public School District will let the GFHNRC to locate its Mobile Nutrition Research Laboratory on school property, and some study activities and measurements will be done in school buildings.

Results of the study (not your individual results) will be given to school administrators, teachers and appropriate health officials (for example, dietitians in the Child Nutrition Program). The GFHNRC will also measure the nutrient content of school breakfasts and lunches, and give the results to school administrators and appropriate health officials.

Who will get the results of this study?

Your individual results will be made available to your parents or guardians. Results from the whole study (not your individual results) will be given to school administrators, teachers and appropriate health officials. A summary of study findings will also be sent to parents/guardians. Your parents/guardians will be strongly encouraged to share and discuss your individual results and the study's findings with you.

What are the benefits of taking part in this study?

You will not be paid any money for taking part in this study. However, you, your school, and society will benefit in several ways if you take part in this study.

You will directly benefit by learning more about nutrition (what we eat and drink) and the importance of nutrition for your health and fitness, how you do in school, your ability to think, and how you feel and socialize with others. You will learn more about many different areas of science, including psychology (the study of behavior), physiology (the study of function), biology (the study of living things), chemistry (the study of substances) and medicine (the study of health and disease). You will even learn some new things related to geography, computers, electricity and mathematics. You will learn about the basics of research and conducting an experiment. We believe your experience with the measurements made during the study, and related classroom activities, will increase your interest in general science and advanced education. And very importantly, by taking part in this study you will gain satisfaction and can take pride from knowing that you took part in an important research study that will benefit society because it will increase knowledge of nutrition and its benefits for all people.

Your school and school district will directly benefit because they will learn more about their students (as a group, not you as an individual) so they can improve their educational programs and benefit future students. Schools will also learn more about their school breakfast and lunch programs.

Your community and society as a whole will benefit because the results will provide important information to scientists, policy makers, nutritionists and other health professionals, and the food industry. These groups need to know whether eating more zinc can help children your age to do better in school, to be more physically fit, and to have better health. The results from this study may be used to help set new dietary guidelines so that more children your age can live healthier and happier lives.

What are the risks of taking part in this study?

Confidentiality

The greatest risk involved in taking part in this study is the loss of privacy (someone getting your personal information). The following steps will be taken to protect your privacy. All information and measurements collected from you will be identified only by your unique school identification number rather than by your name. Only GFHNRC staff will collect and enter your information and measurements into a password-coded computer system. Your information and measurements will not be made available to anyone other than your parents or guardians without their written consent. Everyone involved in the study will be reminded of the importance of protecting every student's privacy. All information and measurements will be kept in a locked file at the GFHNRC for at least three years. When eventually destroyed, any paper that contains your name or personal information will be shredded and any computer disks will be erased. Results from this study may be published in a scientific journal, but only in group form. Any information we collect about your family members also will be kept strictly confidential.

Dietary Treatment

The dietary treatment in this study will be common orange or apple juice that contains different amounts of zinc. Because children your age commonly drink such juice without any ill effects and because the same amounts of zinc have been used in other studies of younger children and adults without any ill effects, there are no known risks of drinking the juice in this study. However, some students may show an allergic reaction to the orange or apple juice. Also, some students may get tired of drinking the same juice 5 days each week for 12 weeks.

Dietary Intake

There are no known risks or discomforts associated with these measurements.

Blood Draw

During any blood draw, there may be some mild pain as the needle enters the skin, but this lasts only a few seconds. A small bruise may develop in about 1 out of every 10 people, but this goes away in two weeks or less. In about 1 out of every 1000 people, an infection may develop where the needle enters the skin, but this is usually treated with common antibiotics. A very few people may feel lightheaded (dizzy) or nauseous (like they need to throw up) for a very short time after their blood is drawn. To reduce this feeling, every student will be given orange or apple juice and a snack immediately following the blood draw, and watched for at least 10 minutes to make sure he or she is okay.

Blood will be drawn under sterile (very clean) conditions with standard needles and syringes similar to those used in your doctor's office or a clinic. Approximately 35 milliliters (2-1/3 tablespoons) of blood will be drawn twice, for a total of 70 milliliters (4-2/3 tablespoons) during the 15-week study. This amount of blood is much less than what was drawn from children your age in a recent national study. Your parent or guardian will be notified if the results of your blood draw show any health problems.

Computer Tasks

There are no known risks associated with performing simple tasks on the computer. However, some students may have concerns about their performance. If you have any concerns about these tasks, you or your parent or guardian can always talk to the field coordinator or principle investigator (Dr. Penland).

Youth Self Report

There are no known risks associated with filling out this questionnaire. However, some students may feel uncomfortable answering some of the personal questions. If you have any concerns about this measurement, you or your parent or guardian can always talk to the field coordinator or principle investigator (Dr. Penland).

Vision and Hearing Tests

There are no known risks or discomforts associated with these tests.

Growth and Body Composition

There are no known risks associated with any of the measurements of growth or body composition. However, some students may feel a little discomfort for a short time when their skin is gently pinched to measure skinfold thickness, and some students may feel a little discomfort for a short time when the adhesive (sticky) tape containing the electrodes are removed after measuring bioelectrical impedance. Measurements at the waist, hip and thigh will be done through the clothing to reduce embarrassment. All growth and body composition measurements will be done behind a portable screen to protect your privacy and a female adult will always be present during measurements of girls.

Physical Fitness

The physical fitness test measures activities commonly done in school physical education classes; therefore, no additional risks or discomforts are associated with this measurement. However, some students may have concerns about their performance. If you have any concerns about this measurement, you or your parent or guardian can always talk to the field coordinator or principle investigator (Dr. Lukaski).

Stopping Dietary Supplements

Although the orange or apple juice used in this study contain vitamins and minerals other than zinc, they will not provide all vitamins or minerals you might be taking now (before the study). Therefore, stopping all dietary supplements to take part in this study may pose a slight risk if you have a very poor diet and usually take such supplements. If you are concerned about this risk, you and your parents/guardians can talk with your physician or dietitian before you agree to participate.

What if I agree to take part in this study, but then decide I don't want to continue?

Participating in this research study is entirely voluntary. You will be free to withdraw from (drop out of) the study at any time. Withdrawing from the study will not affect your status at school, and you will still be able to take part in future GFHNRC studies. Either you or your parent or guardian can contact the study coordinator or the principal investigators if you decide you no wish to participate.

Can I be dismissed from the study?

We have the right to dismiss (drop) you from the study if you do not drink the orange or apple juice each day or do not participate in the measurements described above as scheduled. Minor exceptions may be allowed if they do not interfere with the main objective of the research. For example, if you cannot drink the juice or must reschedule measurements due to a brief illness or absence, you probably will not be dismissed. Each situation will be handled individually, and you and your parent or guardian would be involved in the final decision. Dismissal will not affect your status at school.

What if I get sick or develop a health problem unrelated to this study?

Common illnesses, muscle strains, physical injuries and other health problems may occur at some time during this study, but be unrelated to taking part in the study. Each situation will be handled individually, and discussed with your parent or guardian and if appropriate, with you. If the problem interferes with the research, then you will be dismissed from the study. If the problem does not interfere with the research, then whether or not you continue in the study will be the choice of your parent or guardian and you.

What if I get sick or am injured because I took part in this study?

As described above, there are few known risks associated with taking part in this study. However, the GFHNRC will pay all costs for treatment of any condition caused by taking part in the research study.

Who can answer my questions?

You and your parents or guardians can ask questions about any aspect of this study at any time by asking any member of the GFHNRC staff or by calling the project coordinator, Dr. Jacque Gray, at 701-795-8343, or the principal investigators, Dr. James Penland at 701-795-8471 or Dr. Hank Lukaski at 701-795-8429. You can also let any of the teachers or other school staff know that you have a question and they will have a GFHNRC staff member contact you to answer your question. Any questions about your rights as a research subject can be answered by the Institutional Review Board at the University of North Dakota (701-777-4279).

I understand and agree to take part in this study.

My signature below means that I have read this form and had the study explained to me. I understand what will happen in the study, what is expected of me, and the benefits and risks of participating. My signature on this form also means that I want to take part in this study. I understand that I will receive a copy of this assent form.

PRINT Student Name

PRINT Parent/Guardian Name

Student Signature

Date

Note. Only one parent/guardian is required to give permission.